

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	
_____	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8660

Bartle, J.

August 8, 2011

Bert Levine ("Mr. Levine" or "claimant"), a class member under the Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Dolly Levine, Mr. Levine's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or  
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2003, claimant submitted a completed Green Form to the Trust signed by his attesting physician, John F. Schneider, M.D. Based on an echocardiogram dated July 10, 2003, Dr. Schneider attested in Part II of Mr. Levine's Green Form that claimant suffered from severe mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.<sup>4</sup> Based on such

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3. (...continued)  
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Dr. Schneider also attested that claimant suffered from a reduced ejection fraction in the range of 50% to 60%. This  
(continued...)

findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$297,962.<sup>5</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Leo Wayne, M.D., stated that claimant had "significant myxomatous degeneration of mitral valve leaflet with nearly flail motion of the anterior leaflet." Dr. Schneider, however, attested in claimant's Green Form that Mr. Levine did not suffer from mitral valve prolapse. Under the Settlement Agreement, the presence of mitral valve prolapse requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)b). In addition, although Dr. Schneider attested in claimant's Green Form that Mr. Levine did not suffer from chordae tendinae rupture, he added a handwritten note stating, "(possible) since 3/3/3 [sic]." Under the Settlement Agreement, the presence of chordae tendinae rupture also requires the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(c)ii)c). As the Trust does not contest Mr. Levine's entitlement to Level III benefits, the only issue

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4. (...continued)  
condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.<sup>6</sup>

In July, 2005, the Trust forwarded the claim for review by Michele Penkala, M.D., one of its auditing cardiologists.<sup>7</sup> In audit, Dr. Penkala concluded that there was no reasonable medical basis for Dr. Schneider's findings that claimant did not have mitral valve prolapse or chordae tendinae rupture. In support of this conclusion, Dr. Penkala stated that "[t]here is chordal rupture and marked prolapse/flail of the anterior [mitral valve] leaflet clearly seen on the [parasternal long axis] view. These findings were confirmed at the time of surgery. There is clearly evidence of ruptured chordae to the ant MR and associated prolapse/flail."

Based on Dr. Penkala's findings, the Trust issued a post-audit determination that Mr. Levine was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant

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6. Mr. Levine previously was paid Matrix A-1, Level II benefits. Mr. Levine subsequently submitted this supplemental claim for Matrix A-1, Level III benefits. If Mr. Levine's supplemental claim for Level III benefits is payable only on Matrix B-1, Mr. Levine will not receive any additional payment because the amount to which he would be entitled for his Matrix B-1, Level III claim is less than the amount he already received for his Matrix A-1, Level III claim. See Settlement Agreement § IV.C.3.

7. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims were subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that claimant had a Matrix A-1, Level III claim, the Trust audited Mr. Levine's claim pursuant to the PPP.

contested this adverse determination.<sup>8</sup> In contest, claimant conceded that he suffered from mitral valve prolapse and chordae tendinae rupture but argued he should prevail because these conditions did not exist at the time of his original claim for Matrix Benefits. Claimant also asserted that the presence of these conditions should not bar his recovery of supplemental benefits because they are a result of his ingestion of Diet Drugs.

The Trust then issued a final post-audit determination, again determining that Mr. Levine was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Levine's claim should be paid. On December 9, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5886 (Dec. 9, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting

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8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Levine's claim.

documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 24, 2006. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's findings that he did not have mitral valve prolapse or chordae tendinae rupture. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Levine reasserts the arguments that he made in contest. In response, the Trust argues that Mr. Levine's claim for supplemental benefits was evaluated at the time he qualified for supplemental benefits (i.e., July 22, 2003, the date Mr. Levine underwent surgery to repair and/or replace his mitral valve). According to the Trust, because Mr. Levine suffered from mitral valve prolapse and chordae tendinae rupture at that time, his benefits must be reduced to Matrix B. The Trust also contends that the cause of

Mr. Levine's mitral valve prolapse and chordae tendinae rupture is irrelevant to the resolution of his claim.

After reviewing the entire show cause record, we find claimant's arguments are without merit. As an initial matter, the Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits if he or she is diagnosed with specific medical conditions, including mitral valve prolapse or chordae tendinae rupture. See Settlement Agreement §§ IV.B.2.d.(2)(c)ii)b) & c). As claimant does not contest the presence of mitral valve prolapse and/or chordae tendinae rupture, the Settlement Agreement requires that Mr. Levine's claim be reduced to Matrix B.

We also disagree with claimant that he is entitled to receive Matrix A benefits because mitral valve prolapse and chordae tendinae rupture were not present at the time he submitted his original claim for Matrix Benefits. As reflected on his Green Form for Level III benefits, Mr. Levine's supplemental claim is based on a July 10, 2003 echocardiogram and a July 22, 2003 surgery to repair and/or replace his mitral valve. As stated above, the reviewing cardiologist specifically noted that the echocardiogram demonstrated "significant myxomatous degeneration of mitral valve leaflet with nearly flail motion of the anterior leaflet." In addition, Dr. Schneider determined possible chordae tendinae rupture "since 3/3/3 [sic]." Moreover, in the operative report for claimant's July 22, 2003 surgery, the surgeon, Tom D. Ivey, M.D., noted that Mr. Levine's



"[a]nterior leaflet was two thirds prolapsed with ruptured chordae." Reducing a claim to Matrix B clearly is appropriate where the presence of reduction factors is revealed on the echocardiogram relied upon by claimant for a claim.<sup>9</sup>

Finally, Mr. Levine's argument that he is entitled to Matrix A-1 benefits because his ingestion of Diet Drugs caused his mitral valve prolapse and chordae tendinae rupture is misplaced. Causation is not at issue in resolving Mr. Levine's claim for Matrix Benefits. Rather, Mr. Levine is required to prove that he meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

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9. Additionally, nothing in the Settlement Agreement provides a temporal limitation for the reduction factors of mitral valve prolapse and chordae tendinae rupture. As the Settlement Agreement does not include such limitations for mitral valve prolapse or chordae tendinae rupture, we will decline claimant's request to draft such restrictions into the Settlement Agreement.



Id. at 97. If claimants are not required to demonstrate causation, the converse also is true, namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the regurgitation at issue. The Settlement Agreement unequivocally requires a mitral valve claim to be reduced to Matrix B if the claimant suffered from either mitral valve prolapse or chordae tendinae rupture. We must apply the Settlement Agreement as written. Accordingly, claimant's assertion as to the cause of his mitral valve prolapse and chordae tendinae rupture is irrelevant to the issue before the court.

For the foregoing reasons, we conclude that claimant has not met his burden in proving that there is a reasonable medical basis for finding that he did not have mitral valve prolapse or chordae tendinae rupture. Therefore, we will affirm the Trust's denial of Mr. Levine's claim for Matrix A benefits and the related derivative claim submitted by his spouse.